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October 18, 2001

SUITABILITY PETITION

9896 '01 NOV -2 P2:55

Dockets Management Branch
Food and Drug Administration (HFA-305)
12420 Parklawn Drive (Room 1-23)
Rockville, MD 20857

RE: Suitability Petition

Dear Sir/Madam:

Enclosed are four copies of a suitability petition we are filing on behalf of ANDAFAB ONE LP, ("ANDAFAB") Grand Prairie, TX 75050. The petition requests the Commissioner to permit ANDAFAB to file an abbreviated new drug application (ANDA) for a tableted product containing hydrocodone bitartrate and acetaminophen at strengths different from the RLD drugs as defined in the attached petition.

Sincerely,

Paul W. Carr

Paul W. Carr, P.E., R.A.C.
Regulatory Consultant

cc: ANDAFAB

PWC:pbh

01P-0504

CP 1

SUITABILITY PETITION

Petition Filed By:

ANDAFAB ONE LP
2940 North Highway 360
Suite 100
Grand Prairie, TX 75050

Proposed Products:

Oral Tablet Dosage Forms Containing
10 mg hydrocodone bitartrate/400 mg acetaminophen
7.5 mg hydrocodone bitartrate/400 mg acetaminophen

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SUITABILITY PETITION

The undersigned submits this Suitability Petition under Section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 355(j)(2)(C), which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR §5.10. Petitioner requests the Commissioner of Food and Drugs to make a determination that the drug products hereinafter described are suitable for consideration under an abbreviated new drug application (ANDA).

A. Action Requested

ANDAFAB ONE LP ("ANDAFAB") requests a determination that a drug product containing 400 mg acetaminophen, 10 mg hydrocodone and a drug product containing 400 mg acetaminophen, 7.5 mg hydrocodone in tablet forms for oral administration are suitable for evaluation under an ANDA.

We also request the Food and Drug Commissioner to grant a waiver from the requirements of a pediatric study for a change in dosage form on the basis that this combination of active ingredients is currently approved by the Food and Drug Administration at the above noted strengths as well as several other strength combinations. We understand the agency's desire to seek information regarding the use of this drug in various pediatric populations. However, in this case, the product labeling already includes approved uses and dosing instructions for the most significant patient population. We propose that the concept of a standardized dosage adjustment for safety or efficacy, which is the usual goal of pediatric studies, is not relevant to this drug. In accordance with 21 CFR 314.55(c) the Commissioner may grant full or partial waiver of the study requirements on his own initiative **or** at the request of the applicant.

B. Statement of Grounds

The FFDCA allows an ANDA applicant to petition FDA for permission to file an ANDA for a drug product whose strength differs from that of the listed drug. See 21 U.S.C. §355(j)(2)(C); 57 Fed. Reg. 17950-17952(1992).

In the case of the proposed products there are several reference listed drug (RLD) products for tablets published in, "*Approved Drug Products with Therapeutic Equivalence Evaluations,*" (The Orange Book) covering strengths of acetaminophen from 325 mg to 750 mg along with hydrocodone strengths from 2.5 mg to 10 mg (Attachment 1). In addition to the reference drugs, the Center for Drug Evaluation and Research (CDER) has already approved Endo Pharmaceuticals' tablet products containing hydrocodone bitartrate and acetaminophen, 5 mg/400 mg, 7.5 mg/400 mg, and 10 mg/400mg. The approval letter for these products is found in Attachment 2. Thus there are already on the market products at the same strength as requested in our application. We have also attached a table listing products similar to the proposed products that have been approved or for which suitability petitions have been accepted (Attachment 3).

The proposed products are similar to the reference (RLD) products in that the proposed products contain acetaminophen and hydrocodone in combination, as a proven analgesic, at respective strengths well within those found in the approved products.

The legal basis under which this application proceeds is as promulgated in the FFDCA, noted above, which allows the Commissioner to accept a generic drug application for a drug which differs in dosage strengths from the pioneer or reference drug product. The petitioner is not aware of any information that would be unfavorable to the granting of the requested action.

C. Environmental Impact

ANDAFAB hereby requests a categorical exclusion from the requirement of preparing an environmental assessment. As provided in 21 CFR 25.31, neither an environmental assessment nor an environmental impact statement is required. To the best of the petitioner's knowledge, no extraordinary circumstances exist that may significantly affect the human environment as discussed under 21 CFR 25.21.

D. Economic Impact

As provided in 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. Identification of RLD

ANDAFAB is attaching labeling for products that have strengths bracketing the proposed drugs. However, for purposes of this petition we have only discussed differences between one set of RLD's and our product. These products are as follows:

Application No.	Name of Drug	Company
040148	Norco® 10/325	Watson Pharma, Inc.
040248	Hydrocodone Bitrate and Acetaminophen 7.5/325	Watson Pharma, Inc.

F. Labeling

Attachment 4 provides copies of the proposed generic product labeling and Attachment 5 provides copies of the reference drug labeling.

Following is a description of the differences between the proposed generic product labeling and the RLD package inserts. The immediate product labeling will be revised accordingly.

PACKAGE INSERT

1. Add "Rx Only" to the beginning of the text
2. Removed the Norco® Tablets trade name. Our trade name is yet to be determined and will be in place of the RLD trade name.
3. Removed "National PharmaPak Services, Inc., Zanesville, OH 43701.

- **Description**

    A. Replaced the trade name Norco® with "acetaminophen USP 400 mg and hydrocodone bitartrate USP 10 mg (or 7.5 mg)

    B. Change the descriptive text as follows:

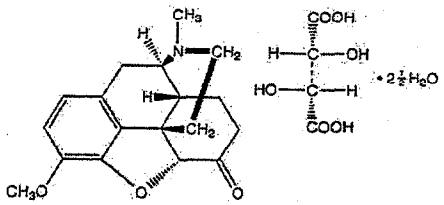
FROM:

DESCRIPTION

NORCO® (Hydrocodone bitartrate and acetaminophen) is supplied in tablet form for oral administration.

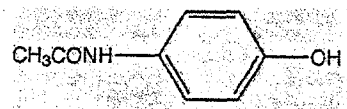
Hydrocodone bitartrate is an opioid analgesic and antitussive and occurs as fine, white crystals or as a crystalline

powder. It is affected by light. The chemical name is 4, 5α-epoxy-3-methoxy-17-methylmorphinan-6-one tartrate (1:1) hydrate (2:5). It has the following structural formula:



$C_{18}H_{21}NO_3 \cdot C_4H_6O_6 \cdot 2\frac{1}{2}\ H_2O$ MW = 494.50

Acetaminophen, 4'-hydroxyacetanilide, slightly bitter, white, odorless, crystalline powder, is a non-opiate, non-salicylate analgesic and antipyretic. It has the following structural formula:



$C_8H_9NO_2$ MW = 151.17

Each NORCO® tablet contains:

Hydrocodone Bitartrate 10 mg (or 7.5 mg)
(**WARNING**: May be habit forming)

Acetaminophen 325 mg

In addition, each tablet contains the following inactive ingredients: croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, pregelatinized starch, povidone and stearic acid; the 7.5 mg/325 mg tablets include FD&C Yellow #6 Aluminum Lake, the 10 mg/325 mg tablets include D&C Yellow #10 Aluminum Lake.

TO THE FOLLOWING:

DESCRIPTION

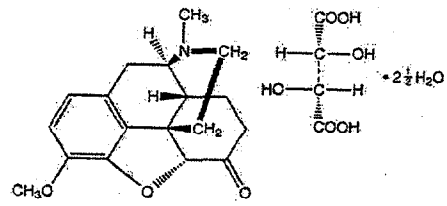
Acetaminophen USP 400 mg and Hydrocodone Bitartrate USP 10 mg Tablets, for oral administration, contain hydrocodone bitartrate and acetaminophen in the following strengths:

Hydrocodone Bitartrate, USP 10 mg (or 7.5 mg)

Acetaminophen, USP 400 mg

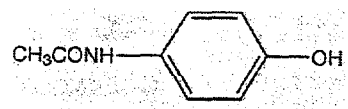
In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, microcrystalline cellulose, and stearic acid. (The 7.5 mg/400 mg tablet contains FD&C Blue No. 2.)

Hydrocodone bitartrate is an opioid analgesic and antitussive and occurs as fine, white crystals or as a crystalline powder. It is affected by light. The chemical name is 4,5(alpha)-Epoxy-3-methoxy-17-methylmorphinan-6-one tartrate (1:1) hydrate (2:5). It has the following structural formula:



$C_{18}H_{21}NO_3 \cdot C_4H_6O_6 \cdot 2\frac{1}{2}\ H_2O$ MW = 494.50

Acetaminophen, 4'-hydroxyacetanilide, a slightly bitter, white, odorless, crystalline powder, is a non-opiate, non-salicylate analgesic and antipyretic. It has the following structural formula:



$C_8H_9NO_2$ MW = 151.17

The above description is similar to the description section for the noted product produced by Endo Pharmaceuticals for the 400 mg/10 mg strength and the 400 mg/7.5 mg strength.

- **Clinical Pharmacology**

  A. Changed "narcotic analgesic" to "opioid analgesic"

- **Indications and Usage**

  A. Changed trade name to generic chemical names

- **Head Injury and Increased Intracranial Pressure**

  A. Changed "narcotics" to "opioids"

- **Acute Abdominal Conditions**

  A. Changed "narcotics" to "opioids"

- **Precautions**

  A. Changed "narcotics" to "opioids"

  B. Changed trade name to generic chemical names

- **Adverse Reactions**

  A. Changed trade name to generic chemical names

- **Drug Abuse and Dependence**

  A. Changed trade name to generic chemical names

  B. Changed "narcotics" to "opioids"

- **Overdosages**

  A. Changes "narcotics" to "opioids"

- **Dosage and Administration**

  A. Added "400 mg/10 mg" before statement and/or "400 mg/7.5 mg" as appropriate

- **How Supplied**

A. Changed statement from:

HOW SUPPLIED

NORCO® is supplied as a yellow, capsule-shaped tablet containing 10 mg hydrocodone bitartrate and 325 mg acetaminophen, bisected on one side and debossed with "NORCO 539" on the other side.

Bottles of 100 NDC 52544-539-01

Bottles of 500 NDC 52544-539-05

Store at controlled room temperature, 15° - 30°C (59°- 86°F). Dispense in a tight, light-resistant container with a child-resistant closure.

Rx only

WATSON PHARMA
A Division of
Watson Laboratories, Inc.
Corona, CA 91720

Revised May 15, 1998

IR5501099 13095-1

TO READ AS FOLLOWS:

HOW SUPPLIED

Acetaminophen USP 400 mg and Hydrocodone Bitartrate USP 10 mg (or 7.5 mg) Tablet is supplied as a white, elongated octagonal, convex tablet embossed with (embossment to be added later)

Bottles of 100
NDC XXXXXXXXX

Bottles of 500
NDC XXXXXXXXX

Store at controlled room temperature 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

A schedule III Opioid. Oral prescription where permitted by State law.

Manufactured By:

PharmaFab
Grand Prairie, TX 75050

PIN 080101 ISS 10/01

Made in USA

G. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to us that are unfavorable to the petition.

Typed Name: PharmaFab Texas, LLC.
A Texas Limited Liability Company
General Partner

Signature Darlene M Ryan

Title: By: Darlene M. Ryan, Its Manager

Name of Petitioner: ANDAFAB ONE LP
Mailing Address: 2940 North Highway 360
Suite 100
Grand Prairie, TX 75050

Telephone No: (972) 408-1101